Complete Summary

GUIDELINE TITLE

Drugs and ethanol. Laboratory medicine practice guidelines: evidence-based practice for point-of-care testing.

BIBLIOGRAPHIC SOURCE(S)

Watson ID, Bertholf R, Hammett-Stabler C, Nicholes B, Smith B, George S, Welch S, Verstraete A, Goldberger B. Drugs and ethanol. In: Laboratory medicine practice guidelines: evidence-based practice for point-of-care testing. Washington (DC): National Academy of Clinical Biochemistry (NACB); 2006. p. 63-75. [70 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Substance and alcohol abuse

GUIDELINE CATEGORY

Screening
Technology Assessment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Pediatrics

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Clinical Laboratory Personnel
Health Care Providers
Hospitals
Nurses
Physician Assistants
Physicians
Public Health Departments
Substance Use Disorders Treatment Providers

GUIDELINE OBJECTIVE(S)

- To examine the application of evidence-based medicine (EBM) to the form of diagnostic testing known as point-of-care testing (POCT)

  Note: For the purpose of this document, POCT is defined as "clinical laboratory testing conducted close to the site of patient care, typically by clinical personnel whose primary training is not in the clinical laboratory sciences or by patients (self-testing). POCT refers to any testing performed outside of the traditional, core or central laboratory."

- To systematically review and synthesize the available evidence on the effectiveness of POCT, with specific focus on outcomes in the areas of:
  1. Patient/health
  2. Operational/management
  3. Economic benefit
- To provide guidelines on the use of POCT for drugs of abuse in medical and nonmedical settings

TARGET POPULATION

Individuals suspected of drug or alcohol abuse

INTERVENTIONS AND PRACTICES CONSIDERED

1. Point-of-care testing (POCT) for drugs of abuse
2. Choosing an appropriate point-of-care (POC) device including careful evaluation of the environment, understanding the limitations of POC devices, staff training in their use and interpretation of results, and use of quality control and quality assurance

Note: The use of POCT for drugs of abuse in the clinical (emergency department, outpatient clinic, obstetric and pain clinics) and nonclinical settings were considered but no recommendations were made due to insufficient evidence.

MAJOR OUTCOMES CONSIDERED

- Sensitivity, specificity, and efficiency of point-of-care (POC) devices and testing
- Error rates for the nonlaboratory personnel
- Economic benefit

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

After the initial questions were agreed upon, the guideline developers found it necessary to perform a broad literature search to identify a sufficient number of papers for review. Pairs of members assessed the papers on the basis of the abstract to identify 100 manuscripts for full review. Additional papers referenced in the reviewed papers were identified and read. Members also consulted their personal manuscript collections. The search strategy used is presented in Literature Search 46 (refer to Appendix B - see the "Availability of Companion Documents" field).

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

I. Evidence includes consistent results from well-designed, well-conducted studies in representative populations.
II. Evidence is sufficient to determine effects, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies; generalizability to routine practice; or indirect nature of the evidence.
III. Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Abstracts identified by the literature searches were reviewed by 2 individuals to determine initial eligibility or ineligibility for full-text review, using Form 1 (Appendix A - see the "Availability of Companion Documents" field). If there was not consensus, then a third individual reviewed the abstract(s). To be included in the full systematic review of the clinical question, articles selected for full text review were examined for at least 1 relevant outcomes measurement. The systematic review consisted of creating evidence tables using Form 2 (Appendix A - see the "Availability of Companion Documents" field) that incorporated the following characteristics:

1. Study design—Prospective or retrospective, randomized, and controlled, patient inclusion/exclusion criteria, blinding, number of subjects, etc.
2. Appropriateness of controls
3. Potential for bias (consecutive or nonconsecutive enrollment)
4. Depth of method description—full-length report or technical brief
5. Clinical application—screening, diagnosis, management
6. Specific key outcomes and how they were measured
7. Conclusions are logically supported

For the assessment of study quality, the general approach to grading evidence developed by the US Preventive Services Task Force was applied (see the "Rating Scheme for the Strength of the Evidence" field). Once that was done, an assessment of study quality was performed, looking at the individual and aggregate data at 3 different levels using Forms 3 and 4 (Appendix A - see the "Availability of Companion Documents" field). At the first level, the individual study design was evaluated, as well as internal and external validity. Internal validity is the degree to which the study provides valid evidence for the populations and setting in which it was conducted. External validity is the extent to which the evidence is relevant and can be generalized to populations and conditions of other patient populations and point-of-care testing (POCT) settings.

The synthesis of the volume of literature constitutes the second level, Form 5 (Appendix A - see the "Availability of Companion Documents" field). Aggregate internal and external validity was evaluated, as well as the coherence/consistency of the body of data. How well does the evidence fit together in an understandable model of how POCT leads to improved clinical outcome? Ultimately, the weight of the evidence about the linkage of POCT to outcomes is determined by assessing the degree to which the various bodies of evidence (linkages) "fit" together. To what degree is the testing in the same population and condition in the various linkages? Is the evidence that connects POCT to outcome direct or indirect? Evidence is direct when a single linkage exists but is indirect when multiple linkages are required to reach the same conclusion.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The field of point-of-care testing (POCT), diagnostic testing conducted close to the site of patient care, was divided into disease- and test-specific focus areas. Groups of expert physicians, laboratorians, and diagnostic manufacturers in each focus area were assembled to conduct systematic reviews of the scientific literature and prepare guidelines based on the strength of scientific evidence linking the use of POCT to patient outcome.

Final guidelines were made according to Agency for Healthcare Research and Quality (AHRQ) classification (see the Rating Scheme for the Strength of the Recommendations field). The guidelines are evidence based and require scientific evidence that the recipients of POCT experience better health outcomes than those who did not and that the benefits are large enough to outweigh the risks. Consensus documents are not research evidence and represent guidelines for clinical practice, and inclusion of consensus documents was based on the linkages to outcomes, the reputation of the peer organization, and the consensus process used to develop the document. Health outcomes, e.g., benefit/harm, are the most significant outcomes in weighing the evidence and drafting guidelines.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Strength of Recommendations

A - The National Academy of Clinical Biochemistry (NACB) strongly recommends adoption; there is good evidence that it improves important health outcomes and concludes that benefits substantially outweigh harms.

B - The NACB recommends adoption; there is at least fair evidence that it improves important health outcomes and concludes that benefits outweigh harms.

C - The NACB recommends against adoption; there is evidence that it is ineffective or that harms outweigh benefits.

I - The NACB concludes that the evidence is insufficient to make recommendations; evidence that it is effective is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

COST ANALYSIS

One study compared the cost of point-of-care urine drug screening in a large manufacturing company with the cost of drug testing in a Department of Health and Human Services (DHHS) –certified reference laboratory. A total of 1101 employees were screened by the US Food and Drug Administration (FDA)-approved point-of-care device, and urine specimens from 56 employees were sent to the referral laboratory for screening. All positive screens were confirmed by gas chromatograph-mass spectrometer (GC-MS). The principal difference between the point-of-care screening and offsite laboratory is related to the elimination of administrative expenses associated with processing negative screens, which at the

point of care were not subject to the same intensity of review as in the offsite laboratory.

The detailed variable cost analysis includes factors representing the labor associated with collecting, processing, and reviewing negative results, and these factors principally account for the cost differential between onsite and offsite drug testing. More specifically, the authors point out that the bulk of the cost savings was due to employee time lost when subjects traveled to offsite collection centers, rather than submitting a specimen at a designated onsite location. There is no indication that the laboratory charge was different for prescreened specimens.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guidelines were presented in open forum at the American Association for Clinical Chemistry (AACC) Annual Meeting (Los Angeles, CA, USA) in July 2004. Portions of these guidelines were also presented at several meetings between 2003 and 2005. Participants at each meeting had the ability to discuss the merits of the guidelines and submit comments to the National Academy of Clinical Biochemistry (NACB) Web site for formal response by the NACB during the open comment period from January 2004 through October 2005.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions of the levels of evidence (I—III) and grades of the recommendation (A, B, C, I) are presented at the end of the "Major Recommendations" field.

Note from the National Academy of Clinical Biochemistry (NACB) and the National Guideline Clearinghouse (NGC)*: The Laboratory Medicine Practice Guidelines (LMPG) evidence-based practice for point-of-care testing sponsored by the NACB* have been divided into individual summaries covering disease- and test-specific areas. In addition to the current summary, the following are available:

- Chapter 1: Management
- Chapter 2: Transcutaneous Bilirubin Testing
- Chapter 3: Use of Cardiac Biomarkers for Acute Coronary Syndromes
- Chapter 4: Coagulation
- Chapter 5: Critical care
- Chapter 6: Diagnosis and Management of Diabetes Mellitus
- Chapter 8: Infectious Disease
- Chapter 9: Occult Blood
- Chapter 10: Intraoperative Parathyroid Hormone
- Chapter 11: pH Testing
- Chapter 12: Renal Function Testing
- Chapter 13: Reproductive Testing

Sample Preparation and Testing

Are there significant differences between point-of-care testing (POCT) devices?

Guideline 83. Once the potential need for POCT is established, a careful evaluation should be conducted by the staff in the environment in which the devices are to be used and on the relevant population.
Strength/consensus of recommendation: A
Level of evidence: II

What analytical accuracy issues affect the use of POCT devices?

Guideline 84. Users of POCT devices should understand any limitations of the devices. This should include the statistical and analytical sensitivity, specificity, and nomenclature of the devices to facilitate their appropriate use.
Strength/consensus of recommendation: A
Level of evidence: I

What knowledge of cross-reactivity of POCT devices is required for their use?

Guideline 85. Users of POCT devices need to be aware of any known interferences from drugs or metabolites that could affect results interpretation.
Strength/consensus of recommendation: A
Level of evidence: I

What are the chief quality issues associated with POCT?

Guideline 86. Purchasers of POCT devices should ensure that users are correctly trained in their use, application, and interpretation. This training should include quality issues and recognition of any device limitations.
Strength/consensus of recommendation: A
Level of evidence: I

What knowledge of sample adulteration is required for the use of POCT devices?

Guideline 87. Users of POCT devices need to be aware of any known interferences from chemicals and other methods of adulteration/manipulation that could affect results interpretation. Procedures need to be adopted within a protocol framework to ensure specimens are tamper free. In critical situations, the type of POCT chosen should enable the tester to detect manipulation by the donor.
Strength/consensus of recommendation: A
Level of evidence: II

Are there significant differences between POCT and central laboratory testing (CLT)?

Guideline 88. POCT for drugs of abuse (DOA) or ethanol may provide adequate information for clinical intervention. Where a definitive penal or legal action is to be taken, laboratory confirmation is mandatory.

Strength/consensus of recommendation: A
Level of evidence: I

Are there significant differences between POCT and CLT?

Guideline 89. POCT screening can be effective, provided quality and data recording issues are addressed. The cost/economic impact needs consideration before introduction. Recording of data is vital, and a legally defensible approach is advised.
Strength/consensus of recommendation: A
Level of evidence: III

Are there significant differences between POCT and CLT?

Guideline 90. There is insufficient evidence for or against specimen stability as a justification for testing location.
Strength/consensus of recommendation: I
Level of evidence: III

Is there an evidence base to confirm that POCT devices perform adequately at detection limits/cutoffs?

Guideline 91. The cutoff(s) should be considered in the selection of a device because these will affect the number of samples requiring confirmation. The statistical likelihood of obtaining a negative result for a sample containing drug near the cutoff should be defined by the manufacturer and presented so that the user who is not a laboratorian can understand the implication of false-negative results. Validation studies during selection and implementation should include testing of the defined cutoff.
Strength/consensus of recommendation: A
Level of evidence: III

What is the impact of quality assurance and quality control (QC) on POCT screening?

Guideline 92. All users of POCT devices must use QC material and participate in external quality assurance (EQA) schemes.
Strength/consensus of recommendation: A
Level of evidence: I

Guideline 93. The decision to use POCT should be a formal corporate decision after a formal evaluation process of the options to ensure fitness for purpose. Only authorized, trained, competency-assessed staff should be allowed to perform POCT within an agreed governance arrangement.
Strength/consensus of recommendation: A
Level of evidence: III

Are there specific quality issues around interpretation of results obtained from POCT devices?

Guideline 94. Procedures must be agreed on and in place to ensure only those recognized by the organization as being competent to interpret POCT results do so. The consequences to the patient/client, analyst, and corporation must be recognized.
Strength/consensus of recommendation: A
Level of evidence: III

Are there specific quality issues for POCT vs CLT?

Guideline 95. All analyses, whether POCT or CLT, must be subject to QC and quality assurance. This should encompass a quality system that includes effective training, recordkeeping, and review.
Strength/consensus of recommendation: A
Level of evidence: II

Use of POCT for DOA in the Clinical Setting

What is the effect on outcome of rapid drug screening in emergency departments (EDs)?

Guideline 96. Although immediacy of POC drug testing results is hypothesized to be useful in an ED, this has not been systematically documented in outcome studies. Therefore, no recommendation can be made at this time.
Strength/consensus of recommendation: C
Level of evidence: I

Guideline 97. There is little cumulated outcome literature to support POCT for DOA in outpatient clinic and outreach clinical settings. Although there are situations where utilization of POCT may enable faster decision making regarding patient disposition, as in an addiction clinic, there is little evidence to support this, and therefore introduction and use should be circumspect.
Strength/consensus of recommendation: I
Level of evidence: III

Guideline 98. There are no outcome studies that support the use of POCT for DOA in obstetric or pain clinics. Although testing for DOA in these settings is often clinically indicated, there is no evidence of added benefit from performing the test at the point of care.
Strength/consensus of recommendation: I
Level of evidence: III

Guideline 99. In clinical settings, the user must be aware of the possibility of sample adulteration/manipulation.
Strength/consensus of recommendation: I
Level of evidence: III

What is the evidence from the literature on the need for confirmation from different population groups?

Guideline 100. Clear guidelines should be developed regarding the need to confirm positive test results using a more sensitive and specific laboratory

method, particularly for situations where definitive punitive action will be taken based on the result. In clinical settings where treatment may be based upon unconfirmed results, staff using the data should be educated with respect to the limitations of the testing.
Strength/consensus of recommendation: A
Level of evidence: I

Urine versus Alternative Matrices

Does the matrix (blood/serum/plasma, saliva, sweat, urine, meconium) affect acceptability for POCT for drugs, and what is the evidence supporting this recommendation?

Guideline 101. Urine is the best established matrix for POCT. Cutoff levels, interferences, and interactions have been established and studied more in urine than in testing with other matrices.
Strength/consensus of recommendation: A
Level of evidence: I

Guideline 102. If alternate matrices are to be used for POCT, the antibodies and cutoffs must be optimized to detect the parent drug or metabolite most abundant in that matrix. Evidence of accuracy and precision must be documented. Sample sites and collection methods for oral fluid, sweat, and breath must be standardized. Sweat sample contamination issues must be resolved before sweat can be considered an acceptable testing matrix.
Strength/consensus of recommendation: I
Level of evidence: II

Guideline 103. Reports using oral fluid for drug screening by POCT demonstrate unsatisfactory results for certain drugs, especially for opiates, delta-9-tetrahydrocannabinol (THC), and benzodiazepine detection. There is a lack of evidence regarding limitations of oral fluid testing.
Strength/consensus of recommendation: C
Level of evidence: II

Nonclinical Applications of POCT for DOA and Ethanol

What is the effect of POCT devices on the outcome of drug testing in nonclinical settings?

Guideline 104. Although drug testing in nonclinical settings may have an overall positive effect of identifying and discouraging drug abuse, there is no evidence that point-of-care drug testing offers any incremental benefit towards those outcomes when compared to conventional testing in a referral laboratory. There may be logistical, and perhaps economic, advantages to point-of-care drug testing, but these benefits are not generalizable.
Strength/consensus of recommendation: I
Level of evidence: II

Are POCT devices reliable for nonclinical applications?

Guideline 105. Although generally reliable in comparison to automated screening methods for DOA, point-of-care devices do not have sufficient specificity to be used for nonclinical applications, and results may be subject to legal challenge unless positive results are confirmed by a definitive method.
Strength/consensus of recommendation: A
Level of evidence: I

How well do nonlaboratory personnel use POCT devices for DOA in urine for definitive actions in nonclinical settings?

Guideline 106. When used by trained laboratory personnel, there is evidence that the current POCT devices for urine drug screening produce results that are comparable to laboratory-based screening methods. When used by trained, nonlaboratory personnel, results are poorer. Policy makers need to decide the acceptable benefit/risk ratio they seek in taking definitive actions; advice from laboratorians should be sought.
Strength/consensus of recommendation: A
Level of evidence: II

Other Issues

Are POCT panels of drugs preferred over single tests?

Guideline 107. If opting to use POCT panels, consider the prevalence of use in the population to be tested for all the drug types on the panel; consider the benefits of single POCT devices in terms of flexibility and cost. Balance this against the breadth of testing available from a central laboratory.
Strength/consensus of recommendation: I
Level of evidence: III

Is there evidence for an economic impact of POCT for DOA and ethanol in any context?

Guideline 108. Independent studies to assess the economic value of POCT for drug testing are urgently needed, particularly given the multimillion dollar nature of the market.
Strength/consensus of recommendation: I
Level of evidence: III

Definitions:

Levels of Evidence

I. Evidence includes consistent results from well-designed, well-conducted studies in representative populations.
II. Evidence is sufficient to determine effects, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies; generalizability to routine practice; or indirect nature of the evidence.
III. Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information.

Strength of Recommendations

A - The National Academy of Clinical Biochemistry (NACB) strongly recommends adoption; there is good evidence that it improves important health outcomes and concludes that benefits substantially outweigh harms.

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C - The NACB recommends against adoption; there is evidence that it is ineffective or that harms outweigh benefits.

I - The NACB concludes that the evidence is insufficient to make recommendations; evidence that it is effective is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

It is hoped that these guidelines will be useful for those implementing new testing, as well as those reviewing the basis of current practice. These guidelines should help sort fact from conjecture when testing is applied to different patient populations and establish proven applications from off-label and alternative uses of point-of-care testing (POCT). These guidelines will also be useful in defining mechanisms for optimizing patient outcome and identify areas lacking in the current literature that are needed for future research.

POTENTIAL HARMS

Point-of-care (POC) screening devices and testing are associated with false-positive and false-negative results.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- The material in this monograph represents the opinions of the editors and does not represent the official position of the National Academy of Clinical Biochemistry or any of the cosponsoring organizations.
- Point-of-care testing (POCT) is an expanding delivery option because of increased pressure for faster results. However, POCT should not be used as a core laboratory replacement in all patient populations without consideration of the test limitations and evaluation of the effect of a faster result on patient care.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Watson ID, Bertholf R, Hammett-Stabler C, Nicholes B, Smith B, George S, Welch S, Verstraete A, Goldberger B. Drugs and ethanol. In: Laboratory medicine practice guidelines: evidence-based practice for point-of-care testing. Washington (DC): National Academy of Clinical Biochemistry (NACB); 2006. p. 63-75. [70 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006

GUIDELINE DEVELOPER(S)

National Academy of Clinical Biochemistry - Professional Association

SOURCE(S) OF FUNDING

National Academy of Clinical Biochemistry

GUIDELINE COMMITTEE

Guidelines Committee

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the National Academy of Clinical Biochemistry (NACB) Web site.

Print copies: National Academy of Clinical Biochemistry publications are available through American Association for Clinical Chemistry (AACC) Press. To make a purchase or request a catalog, contact AACC Customer Service at 202-857-0717 or custserv@aacc.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Preface and introduction. In: Laboratory medicine practice guidelines: evidence-based practice for point-of-care testing. Washington (DC): National Academy of Clinical Biochemistry (NACB); 2006. p. i-xvi.
- Appendix A: NACB LMPG data abstraction forms. In: Laboratory medicine practice guidelines: evidence-based practice for point-of-care testing. Washington (DC): National Academy of Clinical Biochemistry (NACB); 2006. p. 149-153.
- Appendix B: literature searches. In: Laboratory medicine practice guidelines: evidence-based practice for point-of-care testing. Washington (DC): National Academy of Clinical Biochemistry (NACB); 2006. p. 154-186.

Electronic copies: Available in Portable Document Format (PDF) from the National Academy of Clinical Biochemistry (NACB) Web site.

Print copies: National Academy of Clinical Biochemistry publications are available through American Association for Clinical Chemistry (AACC) Press. To make a purchase or request a catalog, contact AACC Customer Service at 202-857-0717 or custserv@aacc.org.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on August 10, 2007. The information was verified by the guideline developer on September 24, 2007.

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